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Harmful or Helpful? Direct-to-Consumer Advertising

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In a given year, Americans are likely to see about 30 hours of advertisements for prescription medications on television (Brownfield, Bernhardt, Phan, Williams, & Parker, 2004). Known as direct-to-consumer advertising (DTCA), this practice refers to the promotion of prescription medications through media including television, magazines, newspapers, radio, and online sources targeting consumers- not just medical professionals (Food and Drug Administration, 2013). Since 1997, the U.S. has been the only other country besides New Zealand that allows the practice due to a change in policy by the FDA (Callaghan, Laraway, Snyckerski, & McGee, 2013).

Defining the Problem

DTCA has been a widely debated issue with strong arguments on both sides. Proponents claim that DTCA strengthens relationships between doctors and patients by creating more informed patients who are engaged with their medical care, increasing acceptance of medication use, educating patients how to advocate for themselves, and informing the public about conditions (Donohue & Berndt, 2004; Holmer, 2002; Kelly, 2004; Myers, Royne, & Dietz, 2011). On the other side of the debate, there is the argument that such advertisements use emotional appeals to convince otherwise healthy people that they are sick and need treatment through medications that they do not need, and that could cause harm (Arney & Menjivar, 2014; Doran & Hogue, 2014; Frosch, Krueger, Hornick, Cronholm, & Barg, 2007; Lemanski & Villegas, 2015; Wolinsky, 2005).

There are risks and benefits to every policy, much like the risks and benefits to taking a medication. In the case of DTCA,

doctors, patients, pharmaceutical companies, and the FDA all have something at stake. This health policy brief presents the history of DTCA, why it came about when it did, and reviews the research supporting both sides of the debate. Finally, alternative approaches to the practice are considered.

Historical Background

Although policy changes to the Food, Drug, and Cosmetics Act (FDCA) in 1997 were the driving force behind DTCA becoming as widespread as it is today, efforts to regulate pharmaceuticals began in the early 1900s. In 1906, the government became more involved in the regulation of food and drugs due to safety concerns for consumers when they implemented the Pure Food and Drug Act. The law put in place labeling regulations to inform consumers about ingredients in medications but did not evaluate their safety or effectiveness (Donohue, 2006; FDA, 2015; Gellad & Lyles, 2007). It also did not stop manufacturers from making statements that exaggerated the effectiveness, claiming it treated a condition when it did not or stopping the use of potentially dangerous chemicals such as cocaine, alcohol, or even poison in the drugs (Donohue, 2006; Mogull, 2008).

Finding this approach to be insufficient in protecting consumers, the Food, Drug, and Cosmetic Act (FDCA) of 1938 was passed, created the FDA, and defined its role in the process of pharmaceutical advertising. Its mission, as it still is today, was to pre-approve medications before they were sold in order to protect consumers and expand labeling regulations to include instructions for use. The 1938 law only focused on medication safety. However, in 1962, the act was amended, adding a requirement that medications also be proven effective before receiving approval for marketing (Donohue, 2006; FDA, 2013; FDA, 2015; Gellad & Lyles, 2007; Mogull, 2008).

The laws described above were prompted by the practice of self-diagnosis/self-medication by consumers and false therapeutic claims being made by manufacturers. To obtain a drug from a pharmacy, even one with potentially dangerous ingredients or side

effects, a person did not need a doctor to write a prescription. The FDCA addressed these concerns by requiring prescriptions for certain medications written by doctors to limit access, a regulation expanded to include more medications in 1951. Another reason for this change was pressure from the American Medical Association that had a strong interest in shifting to doctors being the exclusive gatekeepers to medication. This was in part due to their concern that self-diagnosis could diminish the power dynamic between doctors and patients (Donohue, 2006; FDA, 2015; Mogull, 2008).

After the 1938 law took effect, there was a move away from self-diagnosis and more control over healthcare given to doctors. Pharmaceutical companies also moved their advertising focus exclusively to medical professionals. As a result of this shift, physicians not only prescribed medications, they also were responsible for informing patients of the risks associated with the medication. Some claim that this practice went too far and interfered with patients' rights in healthcare. Concerns about self-diagnosis, self-medication, and the extent of a doctor's role in medical decision making have been an underlying point in the debate over DTCA that continues today (Donohue, 2006; Mogull, 2008).

Evolving Views

From the time the FDCA was passed, concern surrounding the amount of information, and the means by which it was delivered has been debated vehemently. After FDCA, doctors had primary control over information being communicated to patients. Concerns that patients were not receiving adequate risk information led consumer groups to push for alternative ways to access the information that at the time was provided only to doctors (Donohue, 2006; Gellad & Lyles, 2007).

One approach proposed by the FDA was to require patient package inserts (PPIs) with medications to educate patients about the drug's risks. However, the pharmaceutical companies opposed this approach due to high costs of production of the inserts. They also had concern about devaluing the doctor-patient relationship. In response, the FDA relaxed the requirements for PPIs and

instead, only required inserts for specific drug classes rather than all medications (Donohue, 2006).

Conversation surrounding PPIs, mainly the push by consumer groups for distribution of information, led to a change in pharmaceutical companies' thinking regarding DTCA. However, during the 1960s and 1970s, DTCA continued to focus exclusively on advertising to physicians due to strict guidelines. In all advertisements, they were required to communicate all risks and contraindications to consumers. Pharmaceutical companies felt burdened by the amount of information the FDA required as they felt it took away from the promotional nature (Donohue, 2006; Gellad & Lyles, 2007; Mogull, 2008).

In the early 1980s, the first DTCA was put out to the public. After a temporary moratorium put in place by the FDA that ended in 1985, the FDA announced that all pharmaceutical advertisements to consumers had to include the same information that would be communicated to doctors. This essentially restricted DTCA to print form, as it was the only form of media where all information required by the FDA could be included (Donohue, 2006; Mogull, 2008).

Between the initial advertisements in the early 1980s and the current guidelines that were issued in 1997, usage and spending on DTCA grew. Then in 1997, the FDA released new guidelines that took effect in 1999, allowing pharmaceutical companies to advertise through broadcast media for the first time by loosening requirements of communicating risks to consumers. The guidelines put forth in 1997, which will be outlined in further detail below, remain essentially the same today with some changes made in 2006 (Donohue, 2006; FDA, 2013; FDA, 2015b; Gellad & Lyles, 2007; Mogull, 2008).

The Impact of Consumerism on DTCA

During the 1980s and early 1990s, consumer groups became more vocal about the need for awareness about conditions/diseases and risks associated with treatment. This is known as the beginning of the patient and consumer rights movements. The consumer and patient movements called for more transparency in the communication of information and a strengthening of the role

of individuals in their care. In the case of health care, this meant a push for shared decision-making between the doctor and patient. This was in part due to the influence of the aging baby boomers who were more autonomous than previous generations (Donohue, 2006; FDA, 2015; FDA, 2015b).

PPIs were a first attempt at bridging this gap. However, they only informed the person of potential risks after the decision to prescribe was made (presumably based on information by the doctor). DTCA, on the other hand, empowered consumers by providing knowledge prior to meeting with their doctor, allowing for a more informed discussion between the two (Donohue, 2006). Consumerism and autonomy in medical decision-making undoubtedly played a major role in the development of DTCA as it is today.

The Current Law

In 1997, the FDA issued guidelines for pharmaceutical companies that opened the doors for DTCA through broadcast media. These guidelines outline what information must be included in all promotional materials and advertisements. These guidelines differed from past guidelines in that they do not require all risk information to be included. Instead, they must make reference to alternative sources of information such as doctors or toll-free phone numbers (FDA, 2013; FDA, 2015c; Gellad & Lyles, 2007). According to the FDA (2013), three categories of advertisement are used in DTCA: reminder, help-seeking, and product claim.

Reminder advertisements are meant to increase brand recognition and contain only the product's name. Regulations state that advertisements cannot include any information about the purpose of the drug or its effectiveness. The advertisement assumes that the audience is already aware of this information.

Help-seeking advertisements present information about a condition and recommend contacting a medical professional. They do not include names of medications, are not considered an advertisement for the medication, and fall under the Federal Trade Commission. However, if there is only one medication to treat a

condition, these advertisements cannot be used (FDA, 2013; FDA, 2015a; Gellad & Lyles, 2007).

The final category, product claim advertisements, identifies a specific drug and explains the risks and benefits. These advertisements are overseen by the FDA and are required to present specific information. This information includes the name of the drug, FDA approved uses, and major risks of the medication. For television and radio advertisements, all risks must be included, or a list of alternative sources of information regarding risks (such as doctors, website, print advertisement, or toll-free number) must be communicated. For print advertisements, more information, known as the brief summary, is required, which must include an extensive list of side effects, populations who should not take the drug, and when medications should not be taken (FDA, 2015a).

The FDA monitors all advertisements for accuracy and encourages the use of plain language that non-medical people can understand. Although the FDA encourages companies to submit their advertisements for review prior to distribution, companies are not required to have their materials prescreened; instead, the FDA responds, after distribution of the advertisement, to complaints of false or misleading statements made in the material (FDA, 2013; FDA, 2015a).

Examples of misleading information can include claiming a drug is more effective than demonstrated in trials, omitting information about side effects or risks, comparing drugs without evidence, claiming that a drug treats a condition that has not been confirmed by the FDA, and/or giving an unbalanced weighting to the benefits over the risks. If a company is found to be in violation of the FDA's policy, the FDA sends a violation letter, asking the company to discontinue the advertisement. If the FDA feels that the misinformation presented was harmful to consumers, the FDA can require corrective advertising to be distributed to negate the effects. Serious violations are rare, but can result in product seizures and criminal charges (FDA, 2013).

Analysis and Evaluation

Positive outcomes. Proponents of DTCA argue that expanding DTCA would lead to better-informed consumers, who would be more engaged in their healthcare. Results of a survey of physicians by the FDA in 2004 found that physicians overall felt that patients were in fact more involved in their healthcare and asked thoughtful questions regarding treatment options as the result of DTCA (FDA, 2015c). For example, Myers et al. (2011) found that men who had viewed DTCA for Viagra were more likely to engage in a conversation with their doctor about erectile dysfunction. McRoy, Weech-Maldonado, and Kilgore (2014) found that more spending on DTCA was correlated with fewer emergency room visits for asthma among Medicaid-enrolled children.

Negative outcomes. As opponents predicted, many doctors feel that patients are overly confident in the benefits of a drug and are not as informed about the risks associated with medications as is necessary to make an informed decision (FDA, 2015c). A survey found that 78% of doctors felt their patients were able to comprehend the benefits of the advertised drug, but only 40% believed that their patients had a clear understanding of the risks associated with a particular medication. Also of concern was the finding that doctors felt some pressure to prescribe a drug when it was requested, even if they did not feel it was appropriate (FDA, 2015a; FDA, 2015c). Research by Mintzes et al. (2003) found that, compared to Canadians who have little exposure to DTCA, Americans made more requests for advertised drugs and were 17 times more likely to receive that drug from their doctor, supporting the doctors' claims. FDA (2013) policy does not require advertisements to go through a pre-screening process before distribution, creating the possibility for mislabeling and inaccurate information being disseminated to the public. In these instances, corrective action including corrective advertising can be required of the company. However, Aikin et al. (2015) conducted a study that indicated that corrective advertising only works in cases where the effectiveness is overstated, not when risk is not communicated, causing potential harm to consumers.

Cost and profits. In 2014, Americans spent 300 billion

dollars on prescription medications compared to about 100 billion in 1997 (IMS Health, 2015). While research has not shown DTCA to be directly linked to the rise in prescription drug use or cost, a correlation can be observed. The number of new drugs on the market does have an impact on the amount spent by consumers (IMS Health, 2015), and according to Gellad and Lyles (2007), new drugs tend to be the most heavily advertised. This could serve as a possible link between DTCA and prescription drug spending. Studies have demonstrated that DTCA has resulted in increasing conversations about diseases that previously were not discussed or considered. Diseases that were not previously being treated, and now are, such as adult attention deficit disorder, social phobia, depression, erectile dysfunction, and irritable bowel syndrome, could be a driver in rising prescription drug spending. More research would be needed (Arney, & Menjivar, 2014; Conrad & Leiter, 2004; Myers et al., 2011; Wolinsky, 2005).

DTCA is a source of large profits for pharmaceutical companies. In the year 2000, pharmaceutical companies made \$4.20 for every dollar they spent on advertising (Kaiser Family Foundation, 2003). While less money is spent on DTCA than advertising directly to medical providers through medical journals, in 2011, pharmaceutical companies spent 3.9 billion dollars on advertising, representing a significant increase since the introduction of the law in 1997, when 200 million was spent (Encinosa, Myershoefer, Zuvekas, & Du, 2014; IMS Health, 2012).

Opposing Views

Proponents and opponents of DTCA have the same goal in mind: to protect the public from medications that could potentially cause them harm. Proponents generally feel that the more education and autonomy regarding a drug the better, and that DTCA does just that. While opponents do not necessarily disagree with knowledge being key, they express concern that the DTCA provides knowledge through inappropriate avenues and creates a medicalized society. The two sides have strong arguments, both of which should be taken under consideration.

The Benefits of DTCA

The benefits of DTCA focus on the doctor-patient relationship that is strengthened by providing education to the consumer. According to an FDA (2015c) survey, doctors feel that patients had more thoughtful questions and were able to more effectively communicate during appointments. Dens, Eagle, and Pelsmacker (2008) studied differences in attitude towards DTCA and behavior between people in New Zealand (where DTCA is legal) and Belgium (where it is not). They found that people in New Zealand were more likely to seek information about risk than those in Belgium as a result of DTCA. Dens et al. (2008) and Donohue and Berndt (2004) found that even when patients spoke to their doctor about a medication they heard about through DTCA, they did not necessarily receive that medication. Donohue and Berndt also found that advertising directly to doctors, a practice known as detailing, had more substantial effect on which medication was prescribed.

Many critics of DTCA have expressed concerns that DTCA will lead to drug seeking by people who do not need the medication. In an experiment by Callaghan et al. (2013), the researchers found that those who scored high on a depression scale were more likely to report a desire to request Cymbalta than those who scored low. In other words, there was no inappropriate drug seeking, as participants who were most in the need of the medication were the most likely to request it. This study also did not support critics' concerns that viewing DTCA would lead to an increased desire to seek the drug. In fact, this study found the opposite- those who viewed DTCA for Cymbalta were less likely to report a desire to request the drug from their doctor. The authors link this directly to the person's knowledge of side effects and contraindications as a result of viewing the advertisement.

Kelly (2004) and Holmer (2002) point out that drug therapy is effective and can help to prevent the need for hospitalization, thereby lowering healthcare costs. Without DTCA, underserved populations, who might not otherwise have been aware that they had a condition, would have not sought preventative treatment and incurred higher costs in the long run (Kelly, 2004; Holmer, 2002;

Myers et al., 2011). For example, children with asthma who were on Medicaid had less emergency room visits when more money was spent on DTCA, suggesting that increased viewing leads to better health outcomes (McRoy et al., 2014).

DTCA also was found to normalize certain conditions, such as erectile dysfunction and depression; create dialogues between doctors and patients that otherwise would not have happened; and create a better quality of life. Building lines of communication and collaborative relationships between doctors and patients creates more motivation to adhere to a medication regimen because the patient feels that he/she was involved in the decision (Corrigan, Kosyluk, Fokuo, & Park, 2014; Donohue, 2006; Holmer, 2002; Khanfar, Polen, & Clauson 2009; Kravitz et al., 2005; Myer et al. 2011).

The Concerns About DTCA

According to Brownfield et al. (2004), Americans view about 30 hours of DTCA per year. The authors point out that in contrast, people can spend as little as 15 minutes with their doctor in a given year. Considering how often consumers are hearing these messages, it is important that they receive accurate and comprehensive information. While the education DTCA provides to consumers has benefits, critics point out that it is also important to consider that pharmaceutical companies- who profit from the use of the drugs – are the ones designing and funding the advertisements. Advertisements are meant to sell a product for the company, not to altruistically educate the consumer.

A content analysis of DTCA by Frosch et al. (2007) supports this notion; they found that advertisements relied mainly on making emotional appeals by depicting people who are unable to live fulfilling lives without the medications. Lemanski and Villegas (2015) found that a predictor of a person's attitude towards a drug advertised is reliant on multiple considerations including personal experiences with the disease and other individual factors. By depicting characters in the commercials, who viewers relate to DTCA, this can effectively persuade viewers to request the product. Lee, King, and Reid (2015) provide evidence of this as they found that DTCA affects behaviors

of individuals who view them (i.e. requesting medication, using medication). Additionally, in a review of the literature on DTCA, Mintzes (2012) found that nine studies published between 2005 and 2010 supported the notion that DTCA increases demand and prescriptions of medications.

The use of emotional appeals provides support to critics who claim that DTCA leads to medicalization and disease mongering that increases profits for drug companies. In other words, by using DTCA, pharmaceutical companies are expanding the market for diseases and are creating anxiety for healthy people to believe they are sick, or that there is a cure to what was formerly considered an innocuous problem. Pharmaceutical companies do this by using a number of techniques including normalization of the condition, promotion identification through emotional appeals, and facilitation of self-diagnosis by providing symptoms checklists (Arney & Menjivar 2014; Doran & Hogue, 2014; Wolinsky, 2005).

Medicalization and disease mongering, resulting in increased usage, have potentially dangerous consequences for consumers who utilize prescription drugs. The use of prescription medications increased over the course of 10 years. In 2008, 48% of people versus 44% in 1999 used one prescription drug in the last month, and 11% versus 6% used more than 5 (Centers for Disease Control, 2010). Niederdeppe, Byrne, Avery, and Cantor (2013), in a study of statin use for high cholesterol, found that people who were at relatively low risk for heart problems were the driving force behind a rise in usage; however, high-risk patients were no more likely to use statins or be diagnosed with high cholesterol. The authors caution that use of statins in otherwise healthy people can have more negative rather than positive effects. The CDC (2010) notes that poly-pharmacology puts people at higher risk for interactions and side effects of medications. These risks are potentially more harmful than the conditions themselves and include decreased medication adherence and higher health care costs.

While pharmaceutical companies are not entirely to blame for this process, consumers who ask their doctors for the medication and receive a prescription also contribute. The advertisements

act as a driver for spreading the rhetoric surrounding disease and medicalizing life's problems as is the case with Viagra and erectile dysfunction (Myers et al., 2011; Wolinsky, 2005). Myers et al. (2011) found that men who had viewed DTCA for Viagra were more likely to engage in a conversation with their doctor about erectile dysfunction. While some, including the authors, claim this is commendable, it also shows how DTCA is creating demand for treatments for diseases that previously were considered a normal part of aging.

Viagra represents a "lifestyle" drug: a medication that improves quality of life rather than treating a disease. Without DTCA, drugs such as Viagra or Rogaine (for hair loss) may never have been discussed with a doctor as erectile dysfunction and hair loss formerly considered normal parts of aging. Normalizing these conditions creates the need for medications that otherwise would not have existed - the definition of disease mongering (Corrigan et al., 2014; Donohue, 2006; Moynihan, Heath, & Henry, 2002; Myer et al. 2011).

Looking Towards the Future

Throughout its history, arguments promoting DTCA have centered on a desire for distribution of accurate information that provides education to consumers who are taking the drug. Research has shown that conversations between doctors and patients have increased as a result of DTCA, and more people are being treated for diseases than they would have been aware of or treated for previously. Doctors also report that patients who viewed DTCA were more engaged and informed (Corrigan et al., 2014; Donohue, 2006; FDA, 2015c; Gellad & Lyles, 2007; Holmer, 2002; Kelly, 2004; Khanfar et al., 2009; Kravitz et al., 2005; Mogull, 2008; Myers et al., 2011).

While DTCA is one approach that has had some success in bridging the knowledge gap between patients and doctors with regards to risks and benefits of medications, such education is a by-product (Corrigan et al., 2014; Holmer, 2002; Khanfar et al., 2009; Kelly, 2004; Kravitz et al., 2005; Myer et al. 2011). Pharmaceutical companies fund DTCA and use emotional appeals to persuade

viewers that they need a medication, thereby increasing sales and creating profits (Arney, & Menjivar, 2014; Doran & Hogue, 2014; Frosch et al., 2007; Lemanski & Villegas, 2015; Wolinsky, 2005). Also of concern is that research has shown that when consumers are educated about the risks, they are actually less likely to request the medication (Callaghan et al., 2013). This would be a positive finding if other research did not demonstrate that consumers are far more educated about the benefits of a medication than they are about the associated risks (FDA, 2015c). Given this information, it is clear that pharmaceutical companies are profiting from people being under-educated about risks and alternative options of medications presented.

An Alternative Approach

In light of the above evidence, DTCA appears to not be the best means through which to effectively communicate the risks and benefits of medications; however, consumers do need access to information regarding conditions, medications, and therapies for a condition. It is possible that the issue lies in the fact that DTCA focuses on one specific drug rather than educating viewers about multiple options to treat a specific condition.

An alternative to modern DTCA may involve going back to the roots of DTCA. Donohue (2006) points out that disease-specific advocacy groups were a large part of the campaign for DTCA. Another approach may be to turn the task of disseminating information over to these advocacy groups that can promote all treatment options rather than just one medication. For instance, a group that advocates for increased awareness of depression may provide information about alternative treatments such as therapy and lifestyle changes, in addition to multiple antidepressants that are available and the associated risks and benefits through various modes of advertisement.

Given that pharmaceutical companies make large profits from DTCA, it is likely that policy change will be difficult (IMS, 2012; IMS 2015; KFF, 2003). However, if the FDA is committed to educating the public about the risks and benefits of medications, they will see that a change is necessary.

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